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Blakely Sokoloff Taylor & Zafman
12400 Wilshire Boulevard
Seventh Floor
Los Angeles, CA 90025-1030

EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	11

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/040,303	POURMAND ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/17/02*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,57 and 109-124* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,57 and 109-124* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4, 9*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Applicants' cancellation of claims 34, 50, 57, 62, 66, 84, 97, and 98 and addition of claims 110-125 are acknowledged and have been entered.

Election/Restrictions

2. Applicant's election without traverse of claims 1-17, and 57 in Paper No. 10 is acknowledged.

Claim Objections

3. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

4. Misnumbered claims 110-125 been renumbered 109-124.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3, 5-8, 10-13, 17, 57, 109-121, 123 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al [US 5,192,507].

With respect to claims 1 and 57, Taylor et al teach the use of receptor-based or bioaffinity sensors for the determination of an analyte (or a specific class of analytes) of interest in a sample, and to a method of immobilizing and stabilizing a receptor in the bioaffinity sensor. The receptor-based sensor of the present invention includes a polymeric film in which a receptor selected for its capability to bind an analyte of interest is incorporated (column 3, lines 52-58). Taylor et al further teaches the detection of a transient electrical signal produced by a binding event and relating the signal to the occurrence of the binding event (column 7, line 11-column 8, line 30).

7. With respect to claims 2 and 3, Taylor et al teach the use of a sensor to determine an analyte of interest by measuring and detecting the binding event between the analyte and a receptor (column 2, lines 44-66).

8. With respect to claims 5 and 6, Taylor et al teach that the conducting medium sample is a liquid, gel, or gaseous medium (column 3, lines 60-66).

9. With respect to claims 7, 8, 109-112 Taylor et al teach the use of a immobilized receptor for detecting a ligand (column 3, lines 25-31). Taylor et al further teach a sensor comprising a polymeric film comprising a protein, which is a polypeptide (column 16,

example 3). Taylor et al also teach that antibodies and antigens can be used (column 5, lines 12-27, column 11, lines 34-52).

10. With respect to claims 10-12, Taylor et al teach the use of a plurality of electrodes, including a molecule immobilized on the surface of a working electrode ~~electrode~~ (receptor membrane) and a reference electrode (reference membrane) (column 7, line 48 – column 8, line 24).

11. With respect to claims 13 and 17, Taylor et al teach the measurement of impedance (column 8, lines 17-30).

12. With respect to claim 113, Taylor et al teach the use of a biosensor in a fluid medium (column 3, lines 60-66), where an immobilized molecule is a polymer immobilized on a working electrode surface (column 16, example 3), and a transient electrical signal is measured using the working electrode and a reference electrode to measure a movement of a molecule X toward Y, in particular involving binding between X and Y (column 2, lines 44-66).

13. With respect to claims 114-121, 123, Taylor et al teach the use of an immobilized receptor for detecting a ligand (column 3, lines 25-31). Taylor et al further teach a sensor comprising a polymeric film comprising a protein, which is a polypeptide (column 16, example 3). Taylor et al also teach that antibodies and antigens can be used (column 5, lines 12-27, column 11, lines 34-52). Taylor et al also teach that the receptor-based biosensor of the present invention is useful to detect and quantify compounds or substances which act on the receptor (column 5, lines 63-68).

14. Claims 1-5, 7-13, 15, 57, 109-121, 123 are rejected under 35 U.S.C. 102(b) as being anticipated by Lennox et al [US 5,955,379].

With respect to claims 1 and 57, Lennox et al teach a biosensor apparatus for detecting a binding event between a ligand and receptor. The apparatus includes an electrode substrate coated with a high-dielectric hydrocarbon-chain monolayer, and having ligands attached to the exposed monolayer surface. Binding of a receptor to the monolayer-bound ligand, and the resultant perturbation of the monolayer structure, causes ion-mediated electron flow across the monolayer. In one embodiment, the monolayers have a coil--coil heterodimer embedded therein, one subunit of which is attached to the substrate, and the second of which carries the ligand at the monolayer surface (abstract, column 5, lines 45-65)

15. With respect to claim 2, Lennox et al teach the use of detecting binding between a ligand and a receptor (claim 7, column 5, lines 45-65).

16. With respect to claim 3, Lennox et al disclose electrochemical sensors that detect an electrical signal produced by a movement by a first molecule X toward a second molecule Y (claim 7), specifically, the binding of a second peptide to a first peptide.

17. With respect to claim 4, Lennox et al disclose the use of electrochemical sensors that detect an electrical signal produce by a movement by a first molecule X away from a second molecule Y (column 2, lines 42-58). Specifically, Lennox et al discuss the use of electrochemical biosensors comprising two separate reaction elements in the biosensor: a first element contains a receptor and bound enzyme-linked ligand, and the second element, components for enzymatically generating and then measuring an electrochemical species. In operation, analyte ligand displaces the ligand-enzyme

conjugate from the first element, releasing the enzyme into the second element region, thus generating an electrochemical species which is measured in the second element.

18. With respect to claim 5, Lennox et al teach the use of a biosensor used in a fluid conducting medium (aqueous solution) (claim 1).

19. With respect to claims 7-9, 109-112, Lennox et al teach the use of receptors and ligands that are polymers, including polypeptides, antibodies, antigens and nucleic acids (column 13, lines 1-27).

20. With respect to claim 10, Lennox et al teach the use of a biosensor comprised of molecules immobilized on the surface of a working electrode (fig. 2, column 6, lines 22-38).

21. With respect to claims 11 and 12, Lennox et al teach the measurement of a signal using a working electrode and a reference electrode as well as a counter electrode (column 5, line 66 – column 6, line 21).

22. With respect to claims 13 and 15, Lennox et al teach the measurement of the change in current (column 6, lines 11-21)

23. With respect to claim 113, Lennox et al teach the use of a biosensor in a fluid medium (claim 1), where an immobilized molecule is a polymer immobilized on a working electrode surface (column 6, lines 22-38), and a transient electrical signal is measured using the working electrode and a reference electrode to measure a movement of a molecule X toward Y, in particular involving binding between X and Y (column 5, line 66 – column 6, line 21).

24. With respect to claims 114-121, 123, Lennox et al teach the use of a biosensor capable of detecting and quantifying ligand-binding events (column 3, lines 1-10).

Lennox et al teach the use of receptors and ligands that are polymers, including polypeptides, proteins (avidin and biotin), antibodies, antigens and nucleic acids (column 13, lines 1-27). Lennox et al further teaches that the analyte to be be detected may be either member of the binding pair or alternatively, a ligand analog that competes with the ligand for binding to the complement receptor (column 6 lines 22-38).

25. Claims 1-4, 7, 8, 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lowe [Lowe, An introduction to the concepts and technology of biosensors, 1985, Biosensors, 1, 3-16]

Lowe et al teaches the use of a biosensor, comprising a biological sensitive material such as enzyme, multi-enzyme system, antibody, membrane component, organelle, bacterial or other cell, immobilized in intimate contact with a suitable transducing system which converts the biochemical signal into a quantifiable and processable electrical signal (p.6, line 25 – p.7, line 12).

26. With respect to claim 2-4, Lowe et al teaches the measurement of a electrical signal in response to specific and reversible interaction between biological molecules (p.6, line 31 – p.7, line 25).

27. With respect to claims 7 and 8, Lowe et al teaches the use of polymer matrices comprising polypeptides such as cellophane, cellulose acetate/nitrate, polyvinyl-alcohol or polyurethane (p.7, lines 33-40).

28. With respect to claims 13-16, Lowe teaches the use of potentiometric biosensors that measure voltage and accumulated charge (charge density) such as FET devices (p.9,

line 10 – p.12, line 20) and amperometric biosensors that measure current (p.12, line 14 – p.13, line 18).

29. Claims 1-3, 5, 7-13, 15, 57, 109-124 are rejected under 35 U.S.C. 102(e) as being anticipated by Henkens et al [US 6,391,558].

With respect to claims 1-3, 5, 10-12, 57, 113, Henkens et al teach a method involving a polymer Y immobilized on a surface of a working electrode (column 4, lines 41-52), a fluid medium (column 8 lines 63-67), a transient electrical signal from a movement of a molecule X towards Y, specifically binding (column 8, line 67 – column 9, line 5), measured using a plurality of electrodes, including a first working electrode and a reference electrode (column 14, lines 3-12).

30. With respect to claim 7, Henkens et al teach the use of a polymer to coat the sensor (column 43, lines 55-64).

31. With respect to claims 8, 109-111, 114-118, Henkens et al teach that the oligonucleotide sequence of a probe may be bound, bonded, conjugated or otherwise coupled with either a protein, a small molecule such as biotin, or an antibody; or with another molecule, such as fluorescein (Fl) or dioxigenin (DIG), that is able to bond with an electroactive reporter group; or is bonded directly to a biosensor electrode; or is able to hybridize to another molecule, such as an oligonucleotide or protein, such as an avidin, which is bound to a biosensor electrode (column 17, lines 15-30).

32. With respect to claims 9, 112, 119-123, Henkens et al further teach that in an illustrative example, the disclosed methods may be used to detect and quantify a double-stranded PCR.TM. product by tagging one strand and binding that strand to a

NeutrAvidin-coated biosensor, and by tagging the other strand with fluorescein and reacting that strand with an anti-fluoresein HRP conjugate (column 10, lines 23-33). Henkens et al further teaches that the nucleic acid analyte can comprise single nucleotide polymorphisms (SNPs) (column 22, line 36-column 24, line 30)

33. With respect to claims 13 and 15, Henkens et al teach the quantifiable measurement of current on a time scale (column 37, line 1 – column 38, line 54).

34. With respect to claim 124, Henkens et al teach that a method of gene expression profiling. Specifically, Henkens et al teach that profiling tumor microenvironment and genetic makeup at the molecular level provides information for tumor diagnosis and treatment (column 31, lines 11-23).

Conclusion

35. No claims are allowed.

36. The following references are also cited as art of interest: Yamauchi et al [US 5,516,644], Spring et al [US 5,643,721], Say et al [US 6,134,461], Heller et al [US 5,262,305], Cozzette et al [US 5,200,051].

37. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (703) 305-4508. The examiner can normally be reached on 8:30-5:00.

38. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

39. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

NY

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

11/12/03